7. 510(k) Summary

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510(k) Summary – Falcon Spacer	
Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Monika McDole-Russell Regulatory Affairs Specialist Telephone: 610-719-5448 Facsimile: 610-719-5102 Email: mcdole-russell.monika@synthes.com
Date Prepared:	December 21, 2012
Trade Name(s):	Falcon Spacer
Classification:	21 CFR 888.3080 – Spinal Intervertebral Body Fusion Orthopaedic and Rehabilitation Devices Panel Product Code MAX Class II
Predicates:	Synthes Oracle Spacer (K072791) Synthes OPAL Spacer (K072791) Globus Medical PATRIOT TransContinental Spacer (K102313)
Device Description(s):	The **Falcon Spacer** is a radiolucent, oval-shaped spacer intended to be used as an interbody fusion device in conjunction with supplemental fixation. Pyramidal teeth that assist in further stabilization of the construct are located on the inferior and superior surfaces of the spacer. The Falcon Spacer implant may be used to accommodate varying anatomical requirements and is available in a range of heights, sizes and angles. The open architecture of the device is intended to be packed with autogenous bone (i.e., autograft). The **Falcon Spacer** is manufactured from Invibio® PEEK-Optima® LT-1 (ASTM F2026) with four (4) tantalum radiopaque pins (ASTM F-560); The markers allow intra-operative radiographic assessment of the position of the implant.
Intended Use/ Indications for Use:	**Falcon Spacer** is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1 whose condition requires the use of interbody fusion combined with supplemental fixation. The interior of the Falcon Spacer should be packed with autogenous bone graft (i.e., autograft). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should

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	be skeletally mature and have had six months of non-operative treatment. The Falcon Spacer is intended to be used with supplemental fixation.
Comparison of the device to predicate device(s):	The Falcon Spacer is substantially equivalent to the predicate(s) in design, function, performance, material, and intended use.
Performance Date (Non-Clinical and/or Clinical):	*Non-Clinical Performance and Conclusions:* Synthes conducted the following bench testing (as recommended by FDA Guidance and in accordance with ASTM F-2077): ▪ Static Axial Compression ▪ Dynamic Axial Compression ▪ Static Compression Shear ▪ Subsidence ▪ Expulsion Based on information contained herein, Synthes has determined that the Falcon Spacer is substantially equivalent to the predicate devices. *Clinical Performance and Conclusions:* Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Synthes (USA) Products, LLC
% Ms. Monika McDole-Russell
Regulatory Affairs Specialist
1302 Wrights Lane East
West Chester, Pennsylvania 19380

Letter dated: January 8, 2013

Re: K123180
Trade/Device Name: Falcon Spacer
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: December 21, 2012
Received: December 26, 2012

Dear Ms. McDole-Russell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

6. Indications for Use Statement

SYNTHES® Spine

510(k) Number(s): K 123180
(if known)

Device Name: Falcon Spacer

The Falcon Spacer is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1 whose condition requires the use of interbody fusion combined with supplemental fixation. The interior of the Falcon Spacer should be packed with autogenous bone graft (i.e. autograft).

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.
The Falcon Spacer is intended to be used with supplemental fixation.

Prescription Use X (21 CFR 801 Subpart D)	AND / OR	Over-the-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Colin O'Neill

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K123180